

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BARDY DIAGNOSTICS, INC.,)	
)	
Plaintiff, Counter-Defendant)	
)	
v.)	C.A. No. 24-1355 (JDW)
)	
IRHYTHM TECHNOLOGIES, INC.,)	JURY TRIAL DEMANDED
)	
Defendant, Counter-Plaintiff.)	

**DEFENDANT IRHYTHM TECHNOLOGIES, INC.’S THIRD
AMENDED COUNTERCLAIMS AND ANSWER [RESERVED] TO PLAINTIFF
BARDY DIAGNOSTICS, INC.’S SECOND AMENDED COMPLAINT**

Defendant iRhythm Technologies, Inc. (“Defendant” or “iRhythm”), by and through its undersigned counsel, hereby answers the Second Amended Complaint (“SAC”) of Bardy Diagnostics, Inc. (“Plaintiff” or “Bardy”) and asserts counterclaims as follows:

I. IRHYTHM’S COUNTERCLAIMS AGAINST BARDY

iRhythm asserts the following counterclaims against Bardy.

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising from Bardy’s infringement of U.S. Patent Nos. 12,133,734 (the “’734 patent”), 12,245,859 (the “’859 patent”), 12,245,860 (the “’860 patent”), 12,274,554 (the “’554 patent”), and 12,303,277 (the “’277 patent”) (collectively, the “iRhythm Asserted Patents”).

2. iRhythm is the owner by assignment of the ’734 patent. A copy of the ’734 patent is attached as Exhibit 1.

3. iRhythm is the owner by assignment of the ’859 patent. A copy of the ’859 patent

is attached as Exhibit 11.

4. iRhythm is the owner by assignment of the '860 patent. A copy of the '860 patent is attached as Exhibit 12.

5. iRhythm is the owner by assignment of the '554 patent. A copy of the '554 patent is attached as Exhibit 15.

6. iRhythm is the owner by assignment of the '277 patent. A copy of the '277 patent is attached as Exhibit 18.

THE PARTIES

7. iRhythm is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 699 8th Street, Suite 600, San Francisco, CA 94103.

8. On information and belief, Bardy is a corporation organized and existing under the laws of the State of Delaware since 2013.

9. On information and belief, Bardy has its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., including specifically 35 U.S.C. § 271.

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. On information and belief, as a corporation organized and existing under the laws of the state of Delaware, Bardy has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over Bardy.

This Court also has personal jurisdiction over Bardy at least by virtue of Bardy filing the instant action in this Court.

13. On information and belief, Bardy is a commercial entity that makes, uses, advertises, offers for sale, imports, and/or sells ECG monitors and ECG monitoring services. On information and belief, Bardy manufactures, makes, uses, advertises, offers for sale, imports, and/or sells the Carnation Ambulatory Monitor (the “CAM patch”).

14. On information and belief, Bardy sells and offers to sell ECG monitors and ECG monitoring services, including the CAM patch, throughout the United States, including in this judicial district.

15. On information and belief, Bardy makes the CAM patch available to healthcare providers and patients in Delaware.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Bardy is incorporated in the State of Delaware and therefore resides in this judicial district.

BARDY AND BARDY’S CARNATION AMBULATORY MONITOR

17. On information and belief, Bardy is an ambulatory ECG monitoring solutions company founded in 2013, around 7 years after iRhythm was founded in 2006 and after iRhythm had already launched the Zio XT monitor. *See* <https://www.bardydx.com/>.

18. On information and belief, Bardy received FDA approval for the CAM patch no earlier than Dec. 22, 2014. *See* https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143067.pdf.

19. On information and belief, Bardy publicly launched and began commercializing the 2-day CAM patch in the United States no earlier than 2015.

20. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 2-day CAM patch in the United States.

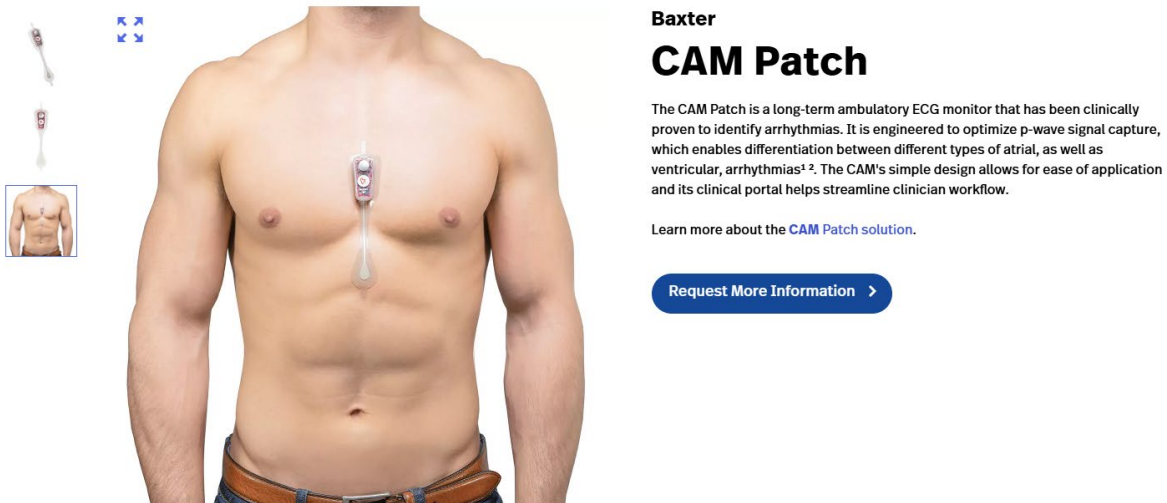
21. On information and belief, Bardy publicly launched and began commercializing the 7-day CAM patch in the United States no earlier than 2015.

22. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

23. On information and belief, Bardy publicly launched and began commercializing the 14-day CAM patch in the United States on or around January 23, 2020. *See* Exhibit 2, Bardy Diagnostics, Inc., “Bardy Diagnostics Announces Commercial Launch of the 14-day Carnation Ambulatory Monitor (CAM) Patch,” PR Newswire (Jan. 23, 2020), <https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-commercial-launch-of-the-14-day-carnation-ambulatory-monitor-cam-patch-300991978.html>.

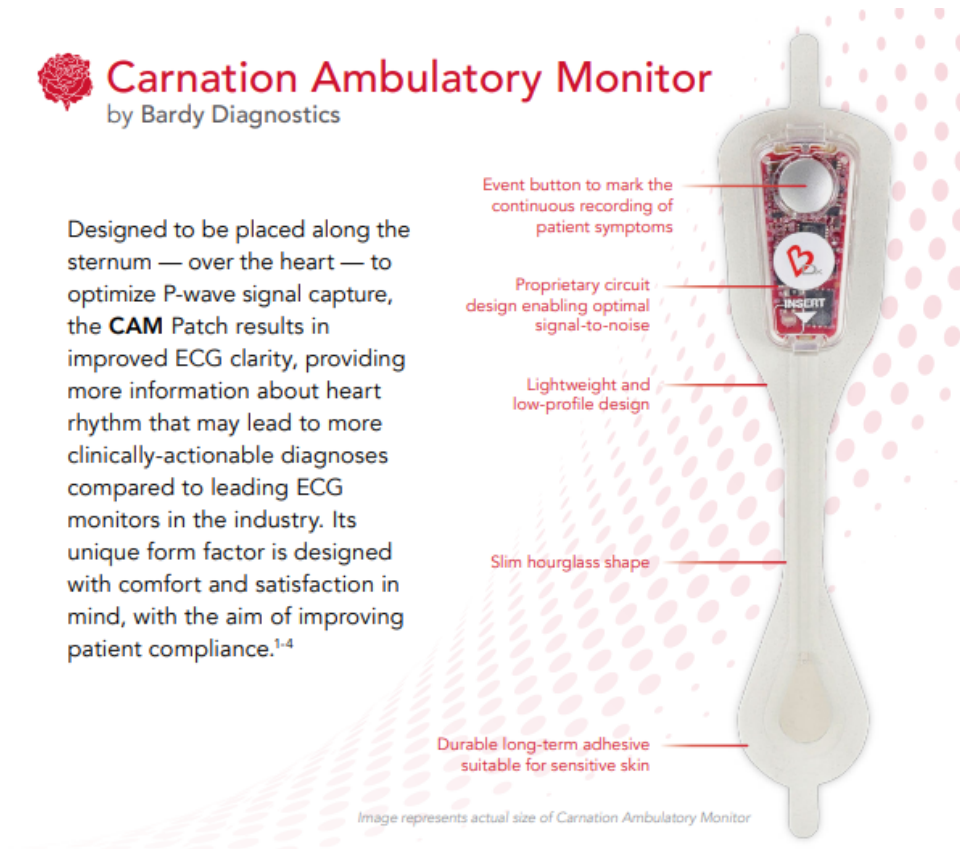
24. On information and belief, Bardy continues to manufacture, use, sell, import, and/or offer to sell the 7-day CAM patch in the United States.

25. The CAM patch is an ambulatory ECG monitor that adheres to a user’s chest. *See, e.g.,* Exhibit 3, <https://www.hillrom.com/en/products/cam-patch/>.



26. As shown below, the CAM patch includes electrodes that capture p-wave signals, “which enables differentiation between different types of atrial, as well as ventricular,

arrhythmias.” *Id.*; *see also* Exhibit 4, <https://www.bardydex.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>. The CAM patch includes a purportedly “proprietary circuit” in a housing that is electronically connected to an electrode located on the patch. Exhibit 5, <https://www.bardydex.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>.



27. On information and belief, and according to Bardy, the CAM patch provides a “[d]urable” adhesion that can last “[u]p to 2, 7, or 14 days.” *See* Exhibit 4.

Technical Specifications

13

TECHNICAL SPECIFICATIONS

ITEM	SPECIFICATION
Performance Characteristics	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 days
Shelf life	24 months

28. On information and belief, and according to Bardy, the CAM patch “captures P-wave signals” from the heart using electrodes and transmits those to a purportedly “[p]roprietary circuit” located on the patch. Exhibit 5; *see also* Exhibit 6, https://www.bardydx.com/wp-content/uploads/2023/07/DN000697B-BDx_CAM_SpecSheet.pdf.

29. Given the facts alleged in this counterclaim, both stated above and set forth below and in Exhibits 7, 13, 14, 16, 17, and 19, Bardy’s CAM patch directly infringes the claims of the iRhythm Asserted Patents, literally or under the doctrine of equivalents.

FIRST COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,133,734

30. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 28 of Section I of iRhythm’s Counterclaims and Answer.

31. The ’734 patent duly and legally issued on November 5, 2024.

32. iRhythm owns all right, title, and interest in the ’734 patent by assignment.

33. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 7, Bardy directly infringes at

least claim 1 of the '734 patent, either literally or under the doctrine of equivalents.

34. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '734 patent.

35. On information and belief, Bardy has had knowledge of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '734 patent.

36. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 7 to this counterclaim to Bardy's counsel.

37. On information and belief, despite having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

38. Bardy has willfully infringed the '734 patent by continuing to make, use, import, offer to sell, and/or sell the CAM patch in the United States after having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent.

39. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

40. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '734 patent.

41. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined,

will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

42. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

SECOND COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,859

43. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 41 of Section I of iRhythm's Counterclaims and Answer.

44. The '859 patent duly and legally issued on March 11, 2025.

45. iRhythm owns all right, title, and interest in the '859 patent by assignment.

46. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 13, Bardy directly infringes at least claim 1 of the '859 patent, either literally or under the doctrine of equivalents.

47. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '859 patent.

48. On information and belief, Bardy has had knowledge of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '859 patent.

49. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 13 to this counterclaim to Bardy's counsel.

50. On information and belief, despite having knowledge of the '859 patent and

knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

51. Bardy has willfully infringed the '859 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '859 patent and knowledge that the CAM patch infringes at least claim 1 of the '859 patent.

52. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

53. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '859 patent.

54. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

55. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

THIRD COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,860

56. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 54 of Section I of iRhythm's Counterclaims and Answer.

57. The '860 patent duly and legally issued on March 11, 2025.

58. iRhythm owns all right, title, and interest in the '860 patent by assignment.

59. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 14, Bardy directly infringes at least claim 1 of the '860 patent, either literally or under the doctrine of equivalents.

60. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '860 patent.

61. On information and belief, Bardy has had knowledge of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '860 patent.

62. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 14 to this counterclaim to Bardy's counsel.

63. On information and belief, despite having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

64. Bardy has willfully infringed the '860 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent.

65. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

66. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '860 patent.

67. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

68. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

FOURTH COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,274,554

69. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 67 of Section I of iRhythm's Counterclaims and Answer.

70. The '554 patent duly and legally issued on April 15, 2025.

71. iRhythm owns all right, title, and interest in the '554 patent by assignment.

72. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim charts attached as Exhibits 16 and 17, Bardy directly infringes at least claims 1 and 4 of the '554 patent, either literally or under the doctrine of equivalents.

73. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '554 patent.

74. On information and belief, Bardy has had knowledge of the issued claims of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the allowed claims of U.S. Patent Application No. 18/936,888, now issued as the claims

of the '554 patent.

75. On information and belief, Bardy has also had knowledge of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '554 patent.

76. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 16 to this counterclaim to Bardy's counsel.

77. On information and belief, Bardy has also had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 17 to this counterclaim to Bardy's counsel.

78. On information and belief, despite having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

79. On information and belief, despite having further knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

80. Bardy has willfully infringed the '554 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent.

81. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a

reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

82. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '554 patent.

83. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

84. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

FIFTH COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,303,277

85. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 84 of Section I of iRhythm's Counterclaims and Answer.

86. The '277 patent duly and legally issued on May 20, 2025.

87. iRhythm owns all right, title, and interest in the '277 patent by assignment.

88. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 19, Bardy directly infringes at least claim 1 of the '277 patent, either literally or under the doctrine of equivalents.

89. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '277 patent.

90. On information and belief, Bardy has had knowledge of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '277

patent.

91. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 19 to this counterclaim to Bardy's counsel.

92. On information and belief, despite having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

93. Bardy has willfully infringed the '277 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent.

94. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

95. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '277 patent.

96. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

97. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

RELIEF REQUESTED

WHEREFORE, iRhythm respectfully requests the following relief:

- A. A judgment and order that Bardy has infringed the iRhythm Asserted Patents;
- B. An order preliminarily and permanently enjoining and restraining Bardy, its officers, directors, agents, servants, employees, licensees, attorneys, and all other persons acting under or through them, directly or indirectly, from infringing the iRhythm Asserted Patents;
- C. A judgment and order requiring that Bardy pay damages under 35 U.S.C. § 284, including an award up to three times iRhythm's damages, as well as prejudgment and post-judgment interest and costs and post-trial damages for any ongoing infringement;
- D. A judgment and order that this case is exceptional and awarding iRhythm its attorneys' fees, costs, disbursements, and interest, as provided by law, including under 35 U.S.C. § 285;
- E. A judgment that Bardy's infringement has been willful, and ordering Bardy to pay treble damages as provided by law; and
- F. Such other and further relief as the Court may deem just and equitable.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, iRhythm respectfully requests a trial by jury in this action for all issues triable by a jury.

II. ANSWER

[RESERVED]

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Attorneys for Defendant

EXHIBIT 18

(12) **United States Patent**
Kumar et al.

(10) **Patent No.:** **US 12,303,277 B2**
(45) **Date of Patent:** ***May 20, 2025**

(54) **DEVICE FEATURES AND DESIGN
ELEMENTS FOR LONG-TERM ADHESION**

(58) **Field of Classification Search**
CPC A61B 5/04; A61B 5/0408; A61B 5/04085;
A61B 5/04087; A61B 5/0492;
(Continued)

(71) Applicant: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(72) Inventors: **Uday N. Kumar**, San Francisco, CA (US); **Peter H. Livingston**, San Francisco, CA (US); **Mark J. Day**, San Francisco, CA (US); **Shena Hae Park**, San Francisco, CA (US); **William F. Willis**, San Francisco, CA (US); **William H. Richter**, San Francisco, CA (US)

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US 8,750,980 B2, 06/2014, Katra et al. (withdrawn)
(Continued)

(73) Assignee: **iRhythm Technologies, Inc.**, San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/806,584**

(22) Filed: **Aug. 15, 2024**

(65) **Prior Publication Data**
US 2024/0398309 A1 Dec. 5, 2024

Related U.S. Application Data

(63) Continuation of application No. 17/304,811, filed on Jun. 25, 2021, now Pat. No. 12,133,734, which is a
(Continued)

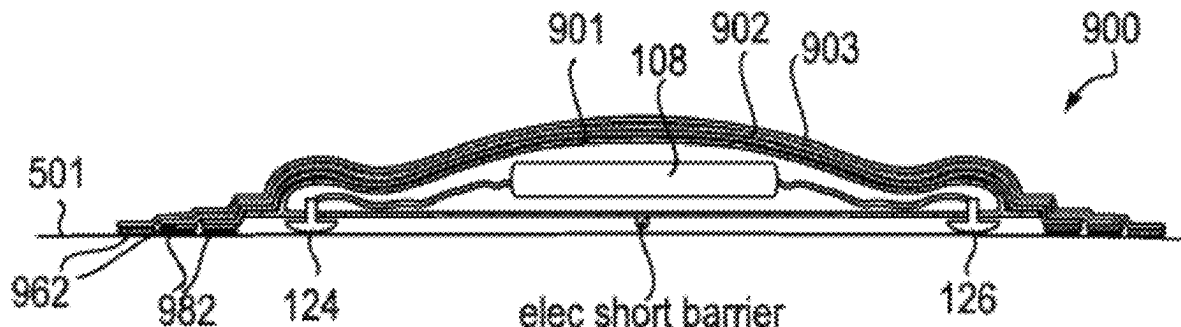
(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/05 (2021.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 5/282** (2021.01); **A61B 5/25** (2021.01); **A61B 5/259** (2021.01); **A61B 5/291** (2021.01);
(Continued)

Primary Examiner — Joseph A Stoklosa
Assistant Examiner — Brian M Antiskay
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers
(Continued)



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from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

10 Claims, 11 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/723,208, filed on Dec. 20, 2019, now Pat. No. 11,141,091, which is a continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

(60) Provisional application No. 61/334,081, filed on May 12, 2010.

(51) Int. Cl.

A61B 5/25 (2021.01)

A61B 5/259 (2021.01)

A61B 5/282 (2021.01)

A61B 5/291 (2021.01)

A61B 5/389 (2021.01)

(52) U.S. Cl.

CPC *A61B 5/6832* (2013.01); *A61B 5/6833* (2013.01); *A61B 5/68335* (2017.08); *A61B 5/389* (2021.01); *A61B 2560/0406* (2013.01); *A61B 2560/0468* (2013.01); *Y10T 156/10* (2015.01)

(58) Field of Classification Search

CPC *A61B 5/0531*; *A61B 5/6801*; *A61B 5/6832–6833*

USPC 600/372, 382–393, 508–509
See application file for complete search history.

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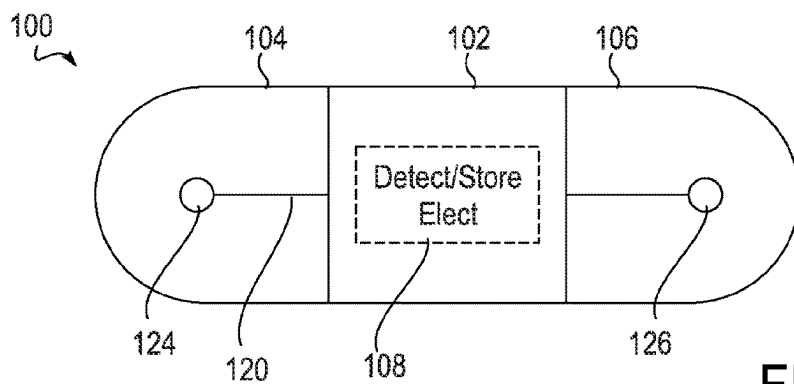


FIG. 1

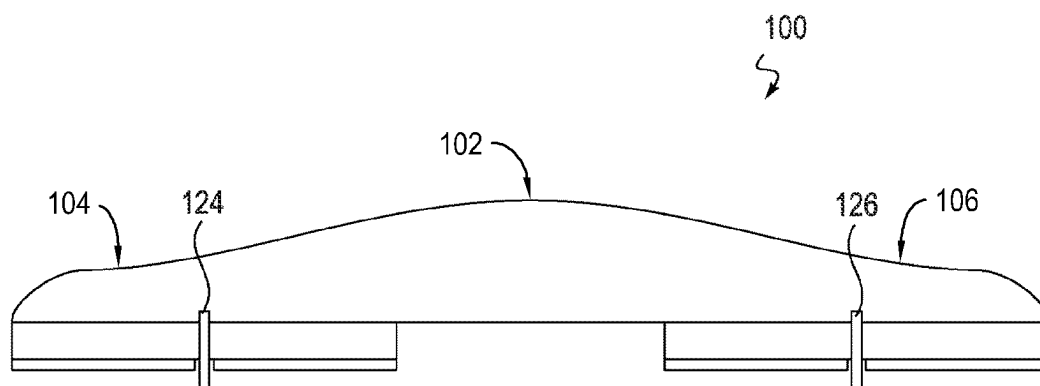


FIG. 1A

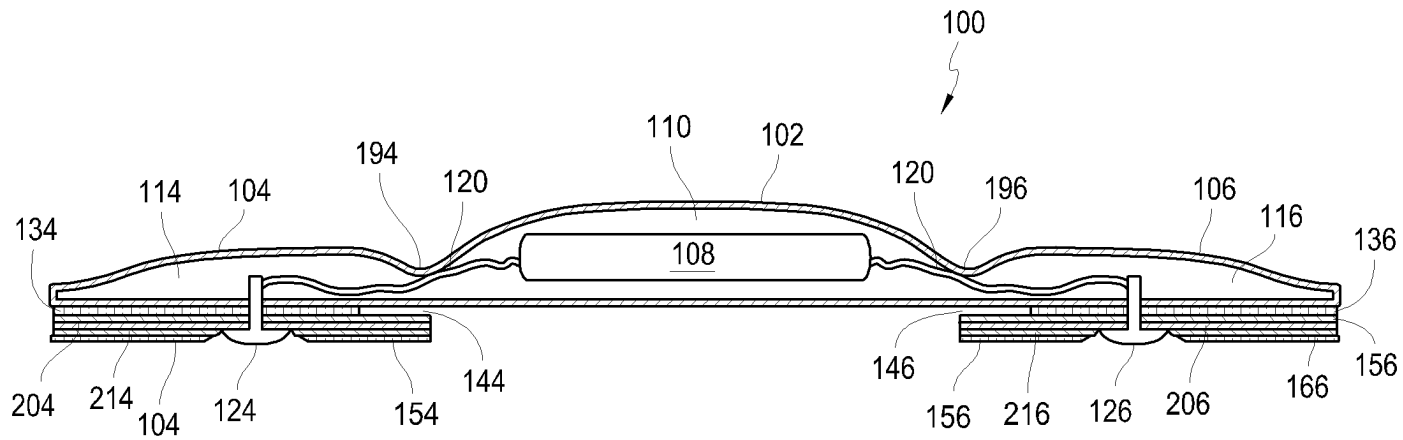


FIG. 1B

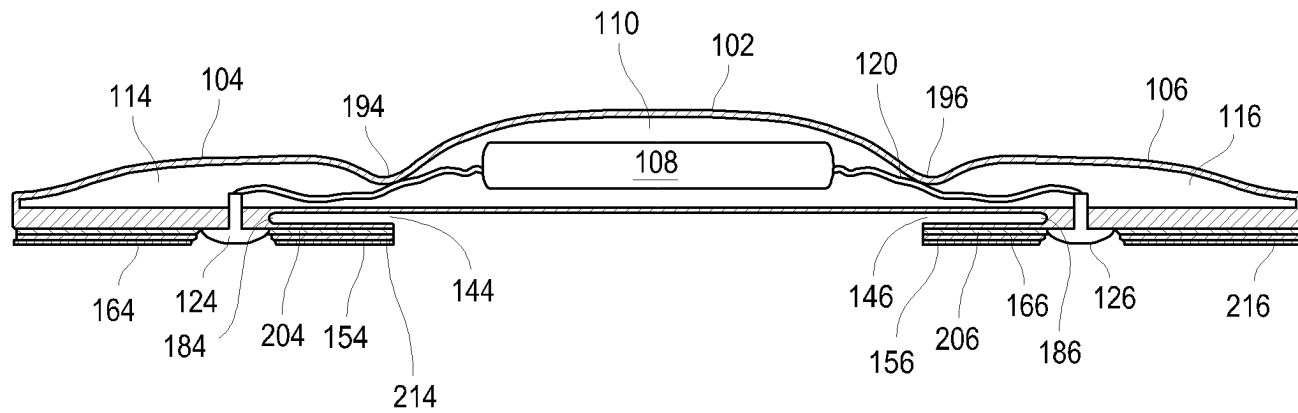


FIG. 1C

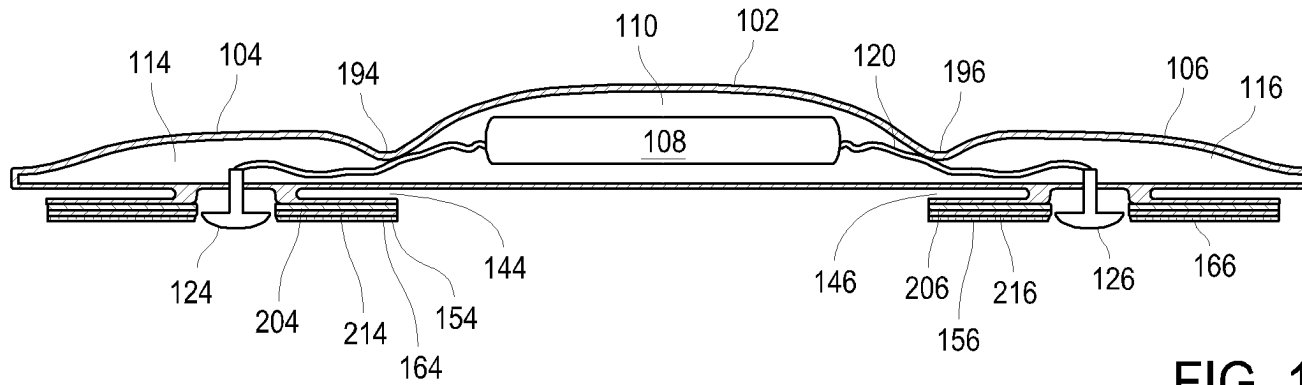


FIG. 1D

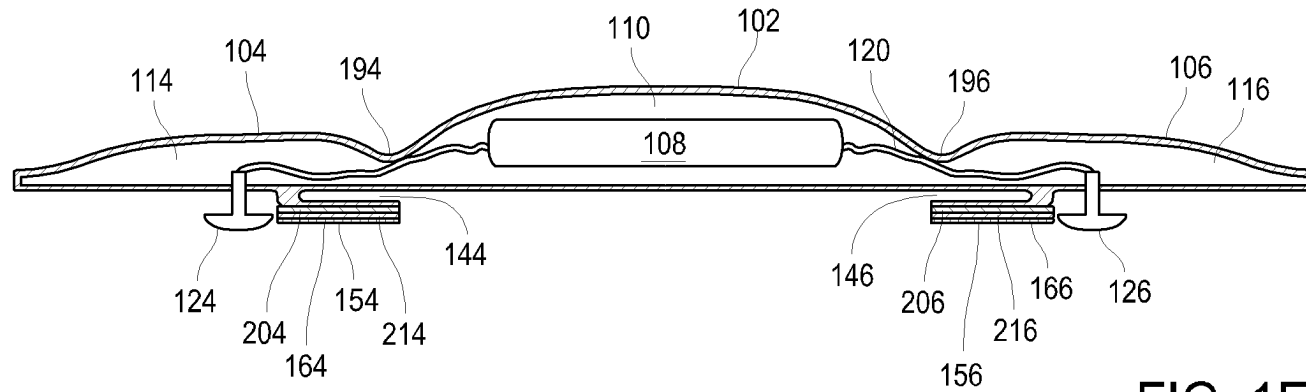
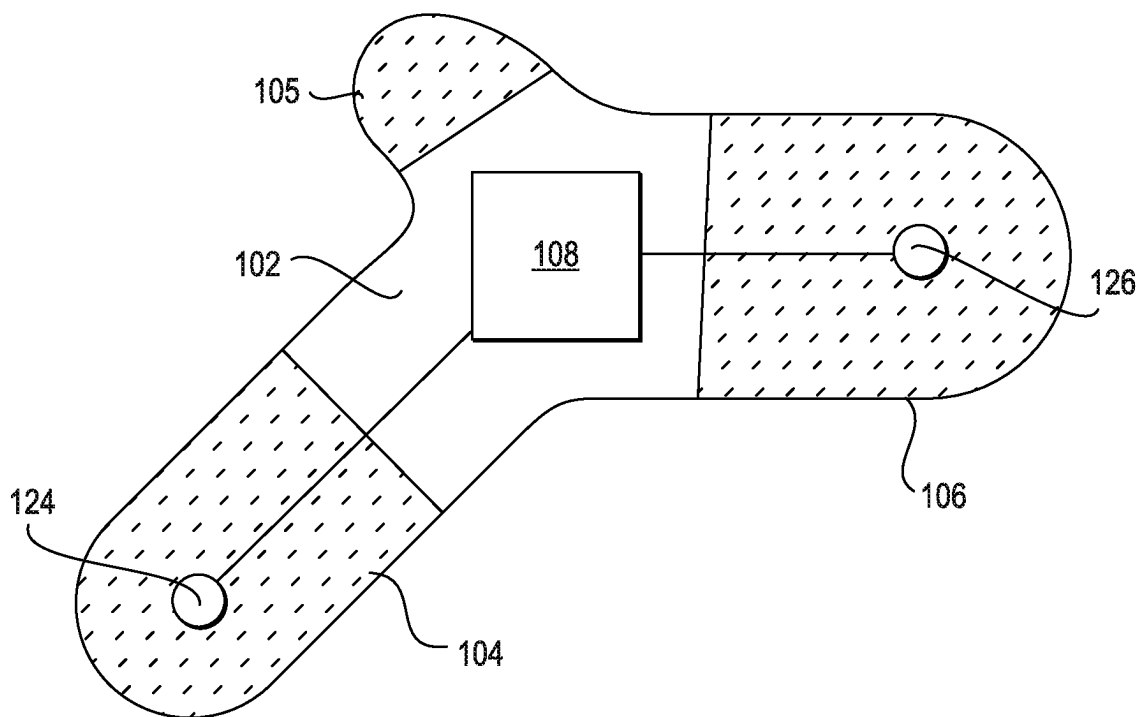


FIG. 1E

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US 12,303,277 B2**FIG. 1F**

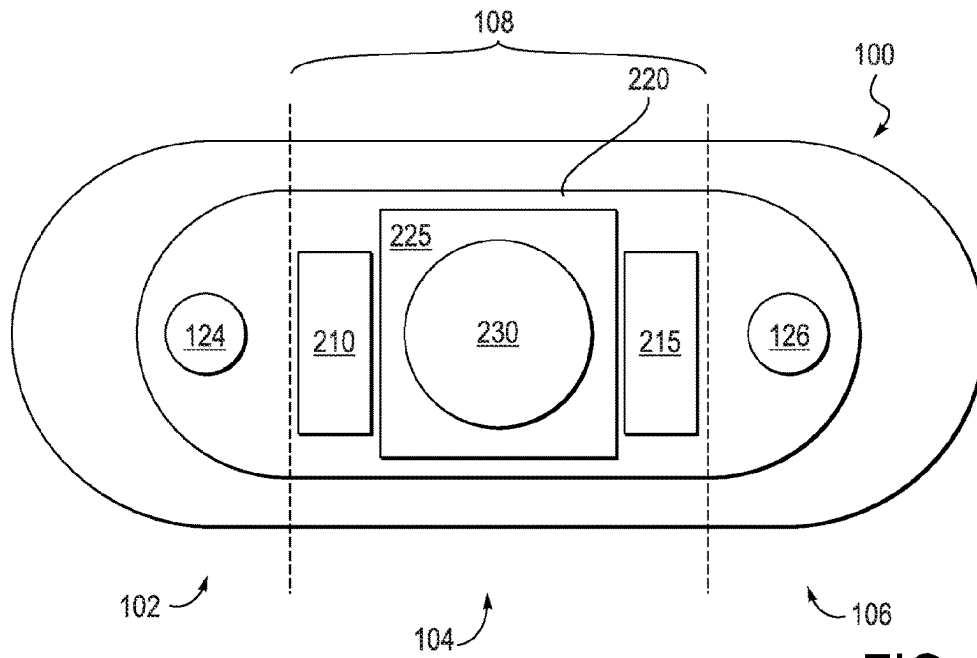


FIG. 2A

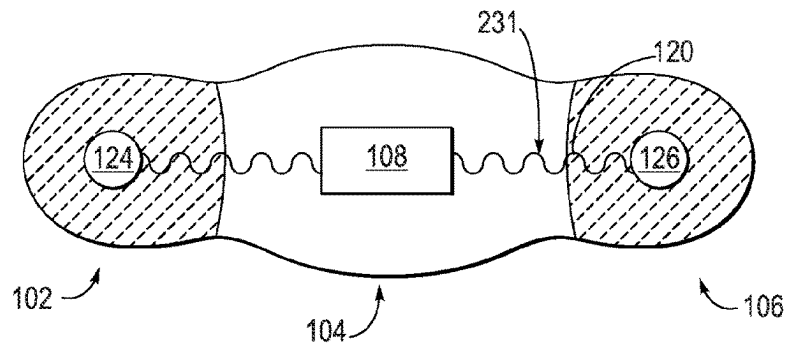


FIG. 2B

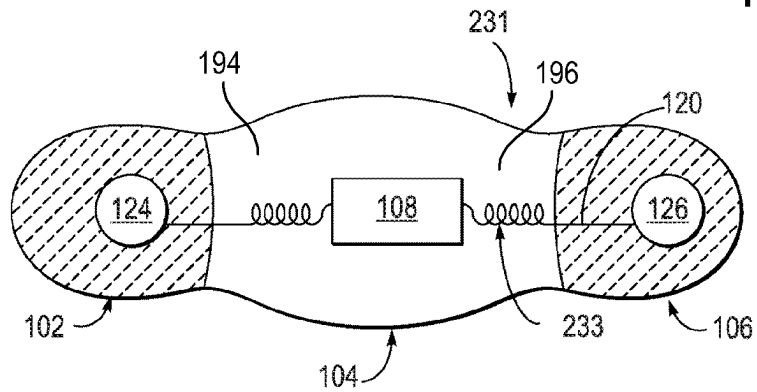


FIG. 2C

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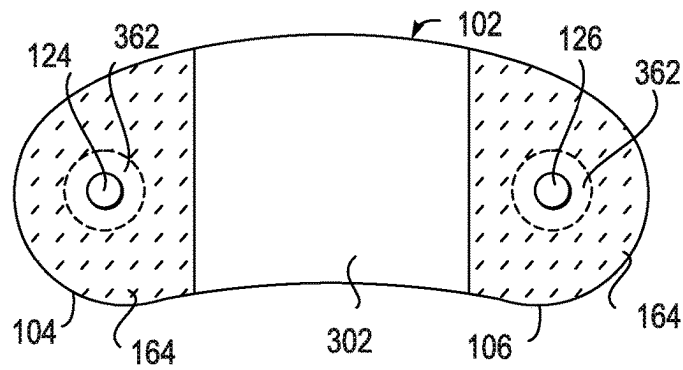


FIG. 3

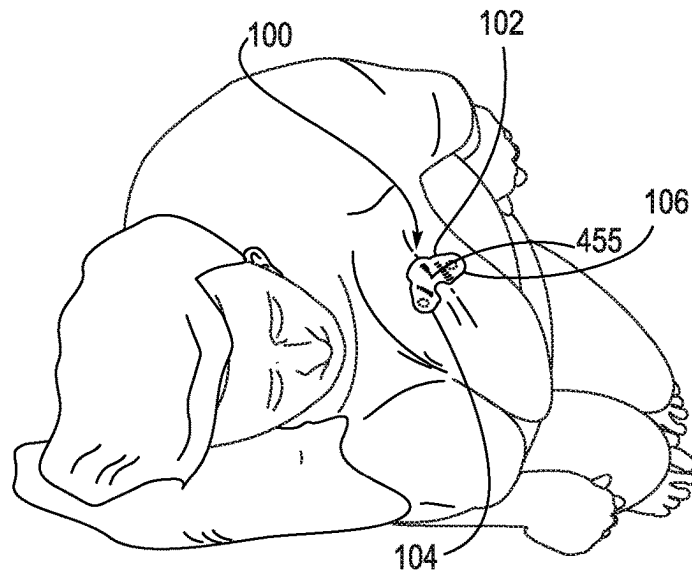


FIG. 4A

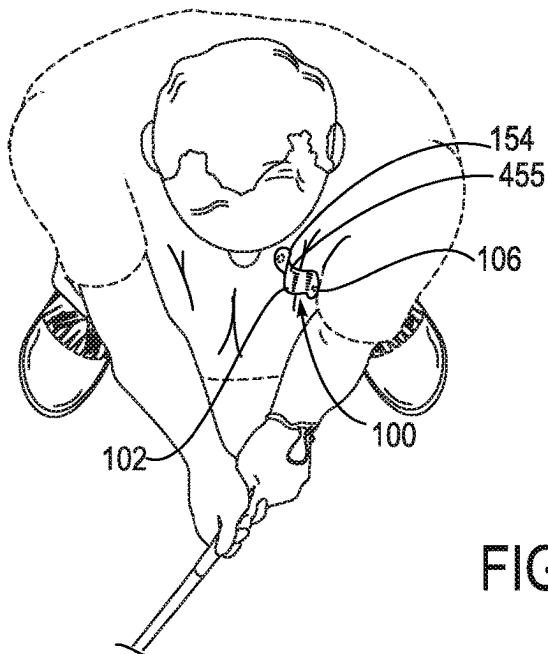


FIG. 4B

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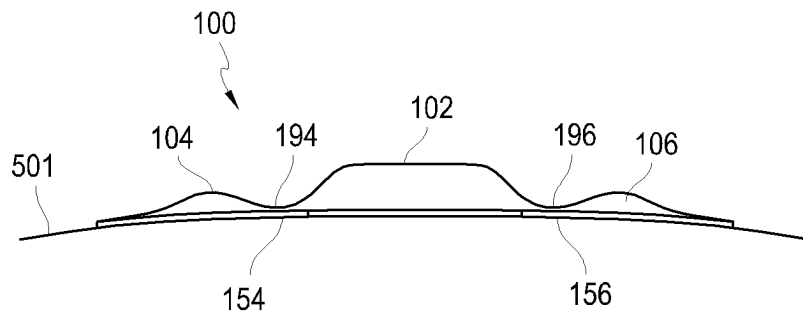


FIG. 5A

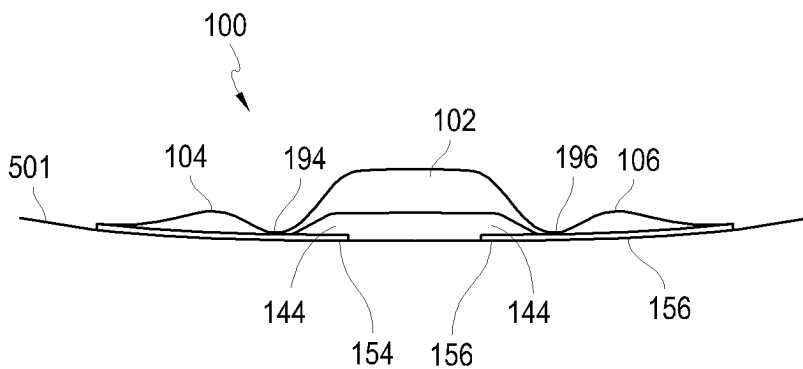


FIG. 5B

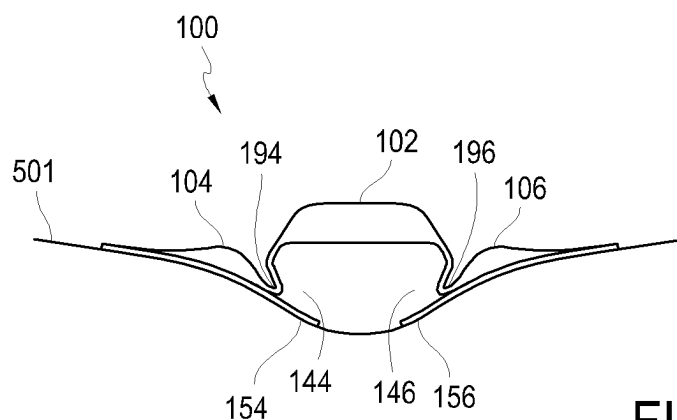


FIG. 5C

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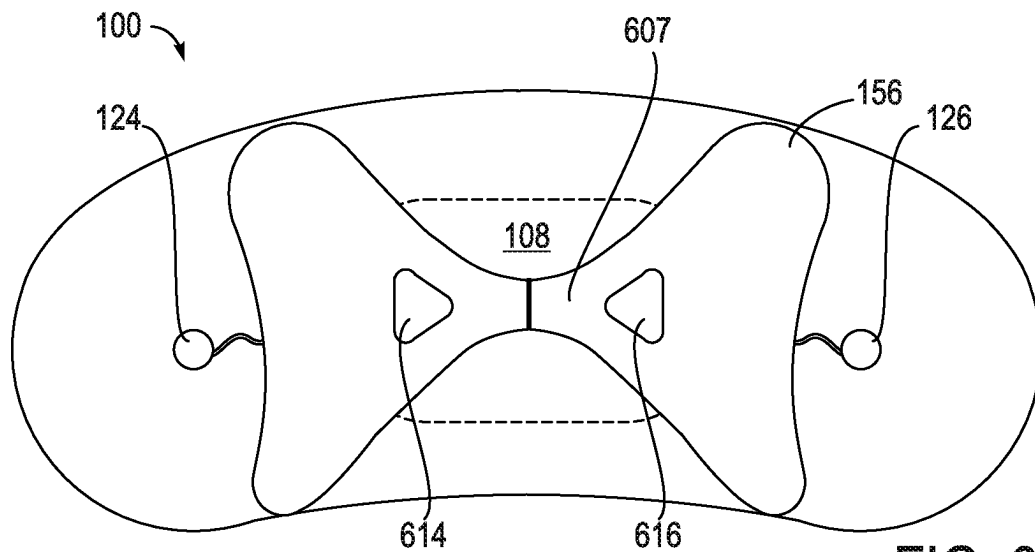


FIG. 6A

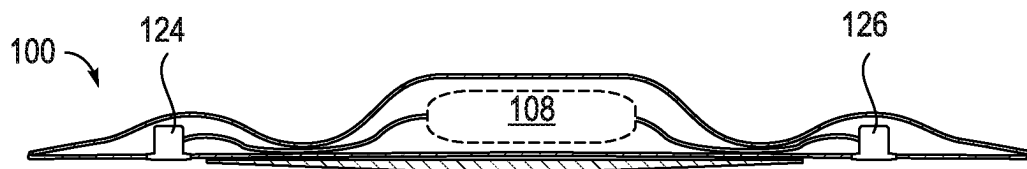


FIG. 6B

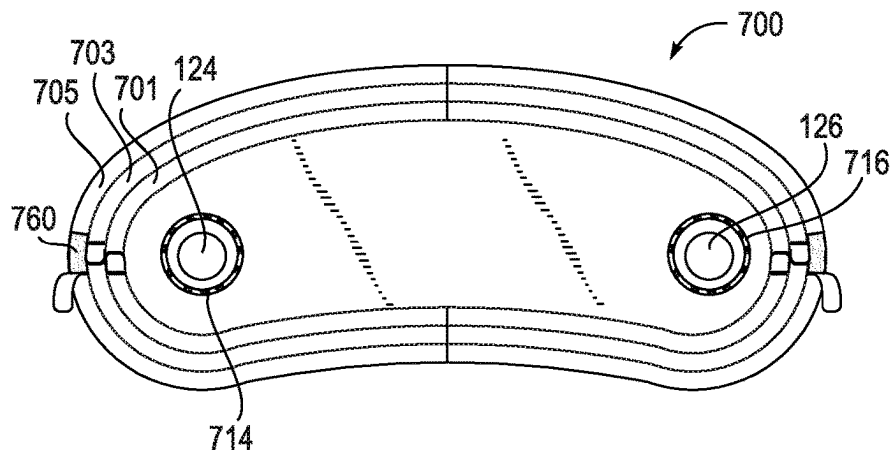


FIG. 7A

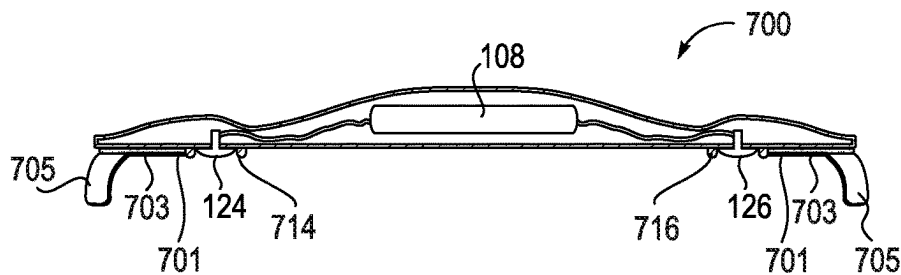


FIG. 7B

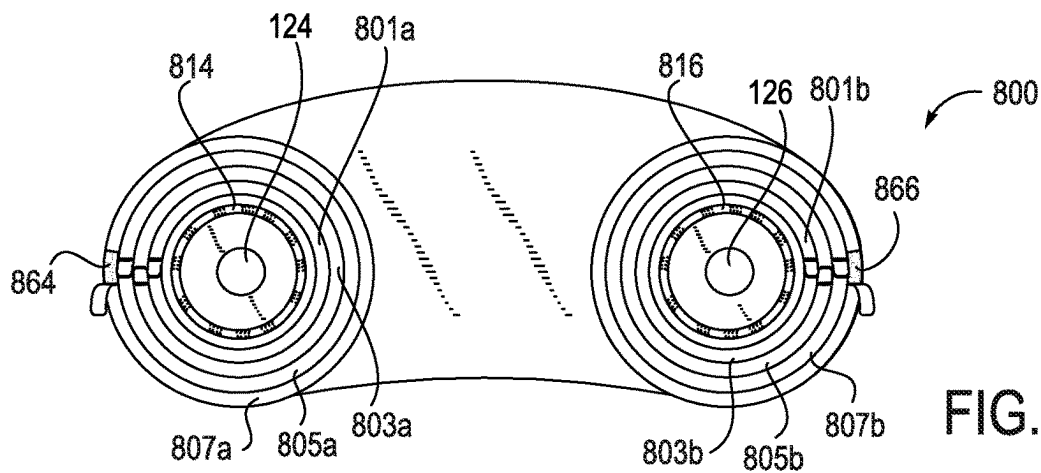


FIG. 8A

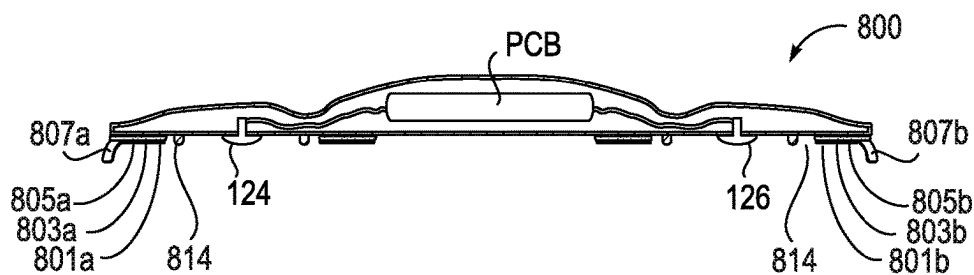


FIG. 8B

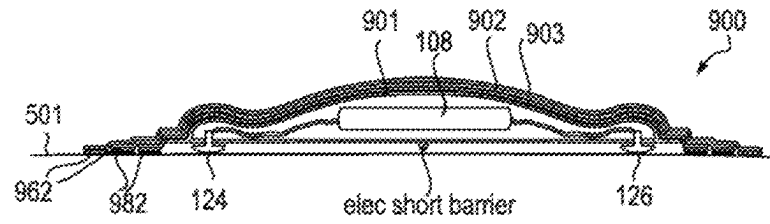


FIG. 9A

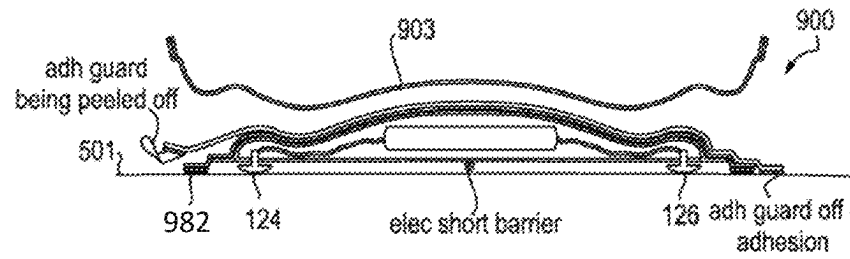


FIG. 9B

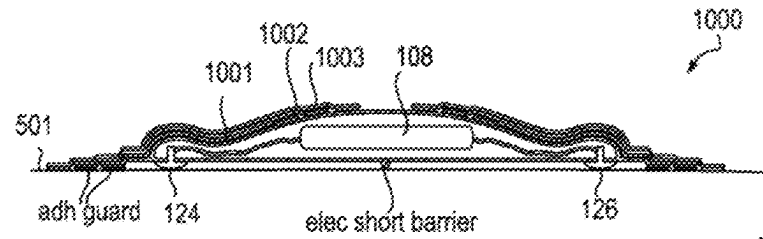


FIG. 10A

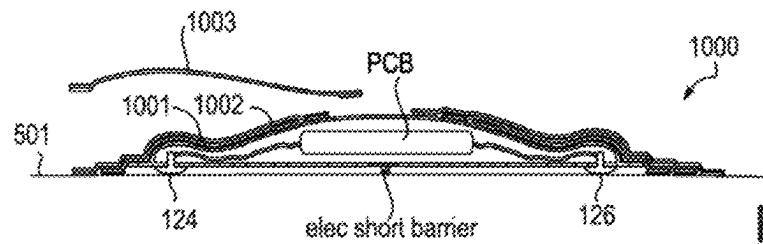


FIG. 10B

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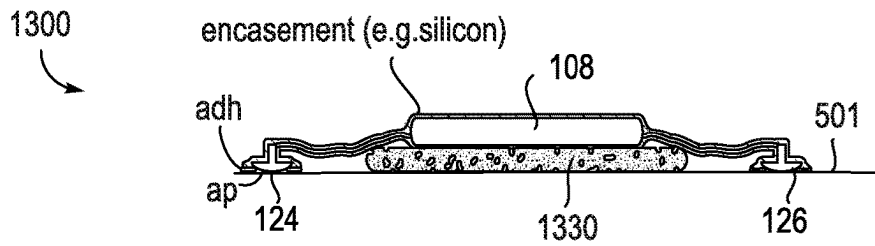


FIG. 11

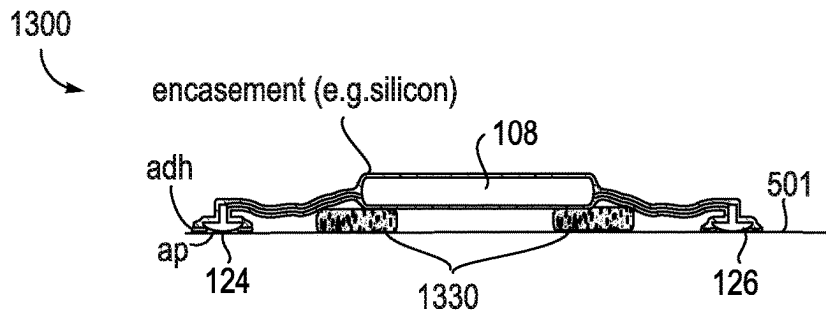


FIG. 12

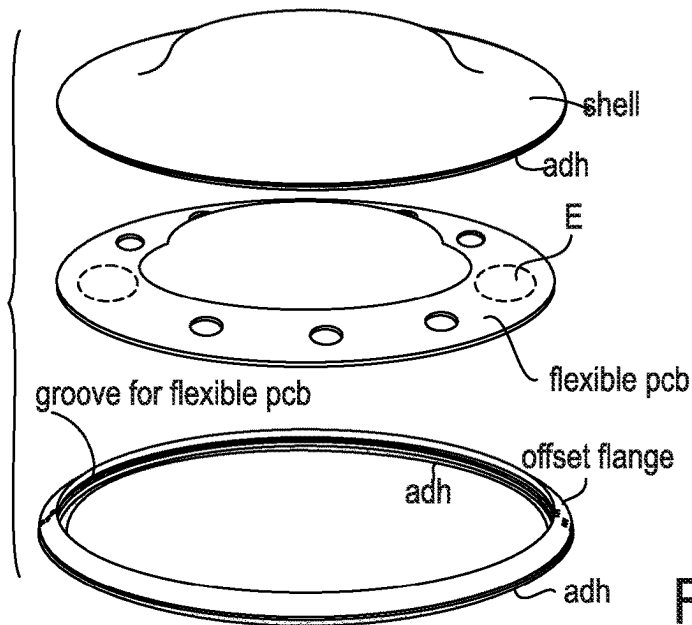


FIG. 13A

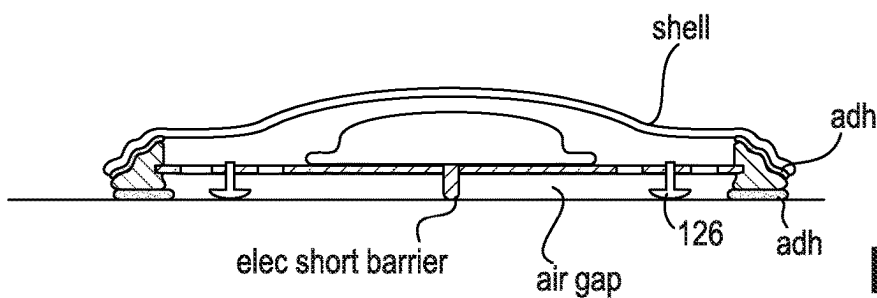


FIG. 13B

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**DEVICE FEATURES AND DESIGN
ELEMENTS FOR LONG-TERM ADHESION****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 17/304,811, filed Jun. 25, 2021, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled "Device Features and Design Elements for Long-Term Adhesion", which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application No. 61/334,081, filed May 12, 2010, entitled "Device Features and Design Elements for Long-Term Adhesion." All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, but not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to

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enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment. In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids.

In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing and wing. The hinge portion is configured to allow the device to bend between the housing and the wing. In one aspect, the hinge portion exists between a rigid

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portion of the device and a flexible portion of the device. In one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wing

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous. In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing. There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes. In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°. In one variation, the angle is approximately 180°. In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip. In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive

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strip. The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips. In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein. There is an electrode positioned on a bottom surface of the patch. The electrode electrically connected to the electronic component. There is a porous foam pad configured to be positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing. There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode. There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an

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adhesive coated on a bottom surface of the second wing and another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bend or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional

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physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for downloading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a top view of a patch having two wings;

FIG. 1A is a representative cross-section of an embodiment of the patch in FIG. 1;

FIG. 1B is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1C is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1D is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1E is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. 2A is a schematic drawing of the electronics contained within a patch;

FIG. 2B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. 2C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. 3 is the bottom view of a patch having adhesive thereon;

FIG. 4A shows a patch as worn by a person rolled to the side;

FIG. 4B shows a patch as worn by a person playing golf;

FIG. 5A shows a patch in response to a concave bend of the skin;

FIGS. 5B and 5C show a patch in response to a convex bend of the skin;

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FIG. 6A is a bottom view of a patch having a connector between two flaps;

FIG. 6B is a cross-section of the patch of FIG. 6A;

FIG. 7A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. 7B is a cross-section of the patch of FIG. 7A;

FIG. 8A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. 8B is a cross-section of the patch of FIG. 8A;

FIGS. 9A and 9B show a patch having multiple layers formed thereon;

FIGS. 10A and 10B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. 11 shows a patch having an open cell support;

FIG. 12 shows a patch having an annular open cell support;

FIG. 13A shows a patch having a protective shell thereon; and

FIG. 13B shows a cross-section of the patch of FIG. 13A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. 1 and 1A, a patch 100 for long term adhesion includes a housing 102. The housing 102 can be formed from any flexible, durable material, such as a bio-compatible polymer, for example silicone. The housing 102 can include electronic components 108 therein. As shown in FIG. 2, the electronics 108 can include a printed circuit board 220, a battery 225, and a communications port mounted on the printed circuit board 220. The printed circuit board 220 can include analog circuits 210, digital circuits 215, and an activation or event notation button or switch 130. The electronics 108 can be used, for example, to record continuous physiological signals from a mammal wearing the patch 100. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. 1 and 1A, wings 104, 106 can be connected to the housing 102. The wings 104, 106 can be integral with the housing 102 and, in some embodiments, can be formed of the same material as the housing 102. The wings 104, 106 can be more flexible than the electronic components 108, which can be substantially rigid. An electrode 124, 126 can extend through a bottom surface of each wing 104, 106. The electrodes can be positioned to detect an ECG of a mammal wearing the patch 100 for processing by the electronics 108. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes 124, 126 can be integral with the wings 104, 106 so as to be inseparable from the wings 104, 106 when the patch is in use.

For a patch 100 that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated.

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Thus, as shown in FIG. 3, an adhesive layer 166 can coat the bottom of the patch 100 for attachment to the skin. For a patch 100 in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics 108), adhesive may be excluded from the portion of the patch 100 underneath these areas. Thus, for example, the bottom surface 302 of the housing 102, which contains the electronics, can remain free from adhesive. As shown in FIG. 1A, by not coating adhesive on a bottom surface of the housing 102, the housing 102 can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. 3 the bottom surface of the electrodes 124, 126 can remain free of adhesive. For example, a ring 362 without adhesive can be formed around each electrode 124, 126 to separate the electrodes from the adhesive 164. The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutylene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings 104, 106 and the housing 102 can form a smooth, contiguous outer surface to the patch 100. As shown in FIG. 1A, when viewed from the top, the housing 102 and wings 104, 106 can together form an oblong substantially oval shape. Further, the housing 102 can have a thickness that is greater than the thickness of the wings 104, 106. The housing 102 and each of the wings 104, 106 when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics 108 can extend along only a portion of the distance between the electrodes 104, 106. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics 108 in a relatively limited space between the electrodes 124, 126, the flexibility of the patch 100 can be increased.

The housing 102 can provide a watertight enclosure 110 for electronic components 108 of the patch 100. The electronics 108 can be unattached to the housing 102 such that the electronics 108 are free to move within the watertight enclosure 110. Allowing the relatively rigid electronics 108 to move freely within the flexible housing 102 advantageously enhances the overall flexibility of the patch 100. The wings 104, 106 can each have a watertight enclosure 114, 116 formed therein, which can be contiguous with the watertight enclosure 110 of the housing 102.

Wiring 120 or other suitable electrical connections can connect the electrodes 124, 126 with the electrical components 108 of the housing. In some embodiments, as shown in FIGS. 1B-1E, the contiguous nature of the enclosure 110 and the enclosures 114, 116 allows the wiring 120 to extend within the patch 100 from the electrodes 124, 126 to the electronic components 108. In other embodiments, one or more channels, tubes, or conduits are provided between the housing 102 and the wings 104, 106, to provide space for the wiring 120. The tube or channel may be straight or curved. In use, the wire 120 positioned in the enclosures 110, 114, 116 or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. 1, the wire 120 is straight with a direct line of connection between the electrodes 124, 126 and the

electronics **108**. FIG. **1** illustrates an embodiment where the length of the wires **120** connecting the electrodes **124**, **126** to electronics **108** are about the same distance as the spacing between the electrode connection point on electronics **108** and the electrodes **124**, **126**. FIG. **1F** also illustrates a straight line type connection where wire **120** length is nearly the same as the spacing between the electronics **108** and the electrodes **124**, **126**. However, as a patient moves, the patch **100** flexes along with patient movement. As shown in FIGS. **4B** and **5C**, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire **120**, the length or shape of the wire **120** may be selected to permit patch flexion to occur with little risk of wire **120** pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags **231** as shown in FIG. **2B**, coils **233** as shown in FIG. **2c**, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit board or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch **100** is attached to a mammal, the slack in the wiring **120** allows the patch **100** to flex while not placing stress on the wiring **120**.

While the illustrated embodiments of FIGS. **1A-1D** show only two wings and show the electrodes and electronics in a direct line in an approximate 180 degree alignment of electrode **124** to electronics **108** to electrode **126**, other configurations are possible. For example, as shown in FIG. **1F**, the wings **104**, **106** are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings **104**, **106** to the housing **102** also illustrates the use of an additional adhesive tab **105**. Tab **105** is shown as a semicircular extension of the body **102**. The bottom of tab **105** can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab **105** may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab **105** can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics **108**.

Referring to FIGS. **1A-1D** and **2B-2C**, a hinge portion **194**, **196** in the patch **100** can extend between each electrode **124**, **126** and the electronics **108**. The hinge portions **194**, **196** can have a thickness less than the thickness of surrounding portions of the patch **100**. For example, if the hinge portions **194**, **196** are in the wings **104**, **106**, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions **194**, **196** can have a width less than adjacent portions of the patch **100**, e.g., less than adjacent portions of the wings **104**, **106**. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics **108**, and a more flexible portion. The hinged portion allows the patch **100** to bend between the housing **102** and wings **104**, **106** to compensate for any movement caused by the patient. As shown in FIGS. **2B** and **2C**, the slack in the wiring **120** can be placed at or proximal to the hinge portions **194**, **196** to allow for bending at the hinge portions **194**, **196** without pulling or breaking the wiring **120**.

Referring to FIGS. **4A** and **4B**, having adhesive on the bottom of the patch **100** except in the areas substantially around the electrodes and directly underneath the housing

102 can create a floating section **455** over the skin of the mammal to which the patch **100** is attached. The floating section **455** can house the more rigid or less flexible electronic components while the flexible wings **104**, **106** can be adhered to the skin and provide the flexibility necessary to hold the patch **100** in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can be mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. **4A**) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. **4B**).

Referring back to FIGS. **1B-1E**, each wing **104**, **106** can include a material layer **214**, **216** between the adhesive **164**, **166** and the wings **104**, **106**. The material layer **214**, **216** can be, for example, a polyester layer. The material layer **214**, **216** can be attached to the patch **100** with a layer of adhesive **204**, **206**. The adhesive **204**, **206** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **204**, **206** could be a silicone adhesive. The material layer **214** can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive **164**, **166** into the wings **104**, **106** or housing **102**. The material layer **214** can thus advantageously serve to maintain the strength of the adhesive **104**, **106** over time.

Referring still to FIGS. **1B-1E**, the patch **100** can further include a first flap **154** connected to the first wing **104** and a second flap **156** connected to the second wing **106**. The flaps **154**, **156** can both extend from a position on the wings **104**, **106** medial to the electrodes to a position below the housing **102**, such as below the electronics **108**. The flaps **154**, **156** can remain unattached to the housing **102**. As a result, gaps **144**, **146** can be formed between the flaps **154**, **156** and the housing **102**. The gaps can provide additional "floating" for the housing **102** and the relatively rigid components **108** contained therein.

In some embodiments, shown in FIG. **1B**, the flaps **154**, **156** can be attached to the wings **104**, **106** with adhesive **134**, **136**. The adhesive **134**, **136** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **134**, **136** could be a silicone adhesive. In other embodiments, shown in FIGS. **1C-1E**, the flaps **154**, **156** can be integral with the wings **104**, **106**. For example, the flaps **154**, **156** can be solvent welded to and/or formed during the molding process of the wings **104**, **105** such that hinges **194**, **196** form below the wings **104**, **106**. Additionally or alternatively, one or more of the flaps **154**, **156** may be separately attached to the wings **104**, **106**. In some embodiments, shown in FIGS. **1B** and **1C**, the materials making up the flaps **154**, **156** can extend all the way to the lateral edge of the patch **100**. In other embodiments, shown in FIG. **1D**, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial—extending flaps are part of the same annular flap. In other embodiments, shown in FIG. **1E**, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps **154**, **156** may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

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shown in FIG. 1F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers 164, 166 can coat all or a portion of the bottom of each of the flaps 154, 156. In some embodiments, the adhesive 164, 166 extends continuously from the bottom surface of the wings 104, 106 to the bottom surface of the flaps 154, 156, except for areas proximate to the electrodes 124, 126. Further, the top surface of the flaps 154, 156, i.e. the surface closest to the housing 102, can remain free of adhesive to ensure that the housing 102 remains floating. In some embodiments, the only portion of the patch 100 including adhesive for adhesion to the skin can be the flaps 154, 156.

Referring to FIGS. 5A-5C, the flaps 154, 156, can provide hinge-like behavior for the patch 100. Thus, as shown in FIG. 5A, if the skin 501 is stretched or bent in a concave manner, the gaps 144, 146 between the flaps 154, 156 and the housing 102 can approach zero such that the patch 100 can sit substantially flat on the skin 501. As shown, the hinge portions 194, 196 between the housing 102 and wings 104, 106 can provide additional flexibility for concave bends by flattening as the patch 100 is stretched. In contrast, as shown in FIGS. 5B and 5C, as the skin 501 is bent in an increasingly convex manner, the gaps 144, 146 between the flaps 154, 156 and the housing 102 can increase, thereby allowing the flexible wings 104, 106 to remain adhered to the skin and the rigid housing 102 to float above skin. As shown, the hinge portions 194, 196 between the housing and the wings 104, 106 can provide additional flexibility for convex bends by folding inward as the patch 100 is bent.

When placed substantially flat on the skin 501, the patch 100 can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than 1 cm off of the skin when floating above the skin. The relatively low height of the patch 100 can enhance long-term adhesion by reducing the potential for the patch 100 to snag or rip off of the skin.

Advantageously, the flaps 154, 156 can function as anchors for adhesion that mitigates shear force. The flaps 154, 156 can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible than the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. 6A and 6B, in one embodiment, the flaps 154, 156 may be augmented by a connector segment

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607 used to join the flaps together. The connector segment 607 can extend below the housing 102, but remain unattached to the housing 102. As shown in FIG. 6A, the flaps 154, 156 and the connector 607 can together form a butterfly shape. In one embodiment, the connector segment 607 and the flaps 154, 156 are formed from a single piece of material. The connector segment 607 can be made of the same material as the flaps 154, 156 or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. 6B, the connector segment 607 can be thicker in the middle, under the housing 102, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment 607 from capturing moisture thereunder. The connector segment 607 can advantageously prevent the device from flipping when attached to the patient

The connector segment 607 can include one or more holes 614, 616. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes 614, 616 can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere long-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or flaps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas. In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch 100 can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body. Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body. A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, or any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

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ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously for more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. 7-10. As shown in the embodiments of FIGS. 7-10, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. 7A and 7B, the patch 700 can be surrounded with an adhesive 760 having multiple covers 701, 703, 705 thereon that can be peeled away in a sequence to expose strips of adhesive 760 underneath. The covers 701, 703, 705 can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch 700. Each additional exposed area of adhesive 760 can increase the adhesion life of the patch 700. Although only three covers are shown in FIG. 7A, other numbers, such as 2, 4, 5, or more are possible. Further, each electrode 124, 126 of the patch 700 can include a barrier 714, 716 to protect the electrodes 124, 126 from shortage.

In another embodiment, shown in FIGS. 8A and 8B, each electrode 124, 126 can be surrounded by a patch of adhesive 864, 866. Accordingly, a set of covers 801, 803, 805, 807 can be positioned sequentially around each of the electrodes 124, 126 over the adhesive 864, 866. The covers 801, 803, 805, 807 can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive 864, 866 can increase the adhesion life of the patch 100. Although only four covers are shown in FIG. 8A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode 124, 126 of the patch 800 can include a barrier 814, 816 to protect from shortage.

Referring to FIGS. 9A-9B, in other embodiments, shells or layers 901, 902, 903 can extend over all or a portion of

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the patch 900. Each layer 901, 902, 903 can include a strip of adhesive 962 on the bottom surface and an adhesion guard 982 protecting the adhesive. As shown in FIG. 913, as the patch 900 is worn over a period of time, the layers 901, 902, 903 can be sequentially removed. As a new layer is exposed, the adhesive guard 982 of that layer can be peeled away such that the adhesive 962 of the new layer can be used to adhere the patch 900 to the skin. In a similar embodiment, referring to FIGS. 10A-10B, each of the layers 1001, 1002, 1003 can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. 7-8, the number of layers in the embodiments of FIGS. 9 and 10 can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. 11 and 12, an open cell structured support 1330 or porous foam can be used to support a more rigid or less flexible portion 1302 of the patch 1300. As shown in FIG. 11, the open cell structured support 1330 can fully fill an area below the rigid portion 1302. Alternatively, as shown in FIG. 12, the open cell structured support 1330 can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support 1302 may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. 13, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. 13A), an oval (see FIG. 1A, 2A), a triangle or generally triangular (see FIG. 1F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. 2B, 2B, 3, 6A, 7A, and 8A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. 3 illustrates a device having a convex surface along the top (where reference 102

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indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124, 126**. FIGS. 2B and 2C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124, 126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes. In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:
a housing comprising a physiologic data collection circuit;

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an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface, the lower adhesive layer providing adhesion to the skin of the user;

an electrode positioned on the bottom surface of the electrode-supporting section, the electrode electrically connected to the physiologic data collection circuit; and wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode; and wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer.

2. The electronic device of claim 1, wherein the electrode supporting section further comprises a third substrate layer adhered to the first substrate layer.

3. The electronic device of claim 1, further comprising an upper adhesive layer positioned on the underside of the first substrate layer.

4. The electronic device of claim 1, wherein the lower adhesive layer extends at least partially below the housing.

5. The electronic device of claim 1, further comprising a flap extending beneath the housing.

6. The electronic device of claim 1, wherein the housing is rigid.

7. The electronic device of claim 1, wherein the housing is configured to remain connected to the electrode-supporting section when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

8. The electronic device of claim 1, further comprising a hinge portion adjacent the housing.

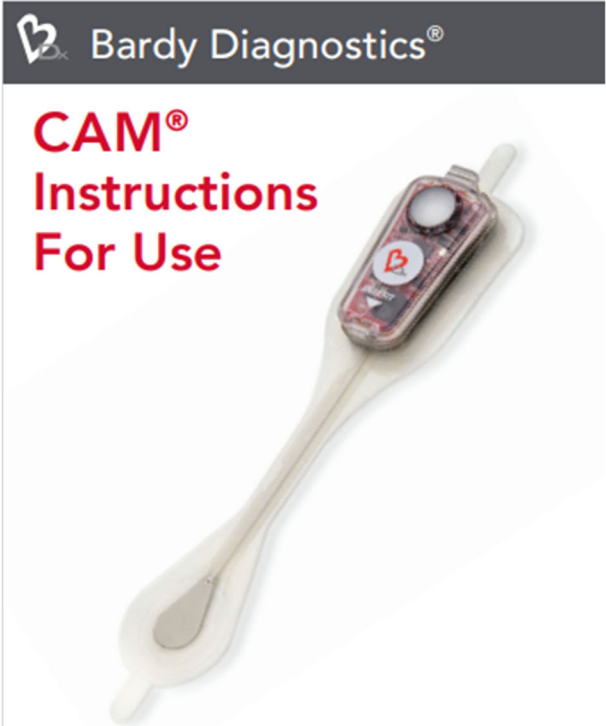
9. The electronic device of claim 1, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

10. The electronic device of claim 1, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

* * * * *

EXHIBIT 19

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

Claim 1	Accused Product
<p>[1.pre] An electronic device for long-term adhesion to a user, the device comprising:</p>	<p>To the extent the preamble is limiting, the Bardy CAM Patch product comprises an electronic device for long-term adhesion to a user, the device comprising.</p> <p>The Bardy CAM Patch comprises an electronic device adhered to a user.</p> <div data-bbox="558 431 1159 1153">The image shows the cover of a user manual for the Bardy CAM patch. At the top, there is a dark grey header with the Bardy Diagnostics logo (a heart with a pulse line) and the text "Bardy Diagnostics®". Below the header, the title "CAM® Instructions For Use" is written in large, bold, red font. In the center, there is a photograph of the Bardy CAM patch, which is a small, rectangular electronic device with a circular display and a Bardy logo, attached to a long, thin, white adhesive strip. At the bottom of the image, there is a red heading "The Carnation Ambulatory Monitor" followed by a description: "is a continuously recording P-wave centric® ambulatory ECG patch monitor that records for up to the prescribed wear time." Below this, there is a blue hyperlink: "(https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf)".</div> <p>The Carnation Ambulatory Monitor is a continuously recording P-wave centric® ambulatory ECG patch monitor that records for up to the prescribed wear time.</p> <p>(https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf)</p>

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

Symbols

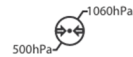
12

SYMBOL

DESCRIPTION



Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.



Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.



Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.



Date of manufacture



Contains electronic equipment. Dispose of properly in accordance with local regulations.

(<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>)

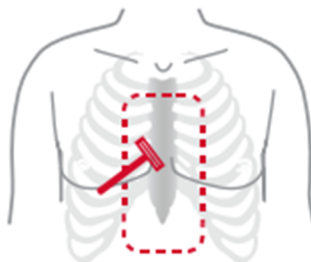
**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

Instructions For Use

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PREPARE THE SKIN

⚠ CAUTION: Proper skin prep required to achieve full length of prescribed monitoring duration.



Step 1

Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the CAM will be placed.

Step 2

Use all prep pads provided in the box to clean area shown. SCRUB the skin with the prep pads until they appear clean after use. Skin should be scrubbed well enough to be slightly reddened. Allow the skin to dry for 2 minutes prior to applying.



PREPARE THE CAM

Step 3

On a flat, hard surface insert the narrow end of the Recorder into the Battrode first with the event button facing up, and then push the Recorder down firmly.

<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

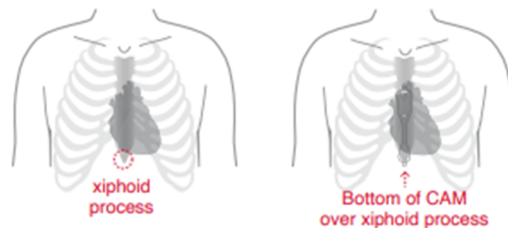
Instructions For Use

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APPLY THE CAM

Step 6

Locate the bone at the bottom of the sternum. This is the xiphoid process.



Apply the CAM to the patient's sternum with the bottom electrode of the patch sitting over the xiphoid process. Press along the entire edge of the patch for 2 minutes and rub firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers below the event button and press down firmly to adhere the top of the CAM to the patient's chest.

RECORD SYMPTOMS



Step 7

Instruct patients to gently press the button only once each time they feel symptoms, and record the date/time in the Patient Diary (included). Do not press button repeatedly or forcefully.



(<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

	<div data-bbox="569 240 730 521"></div> <div data-bbox="709 233 1226 802"></div> <div data-bbox="1289 233 1890 581"><p>Baxter</p><h2>CAM Patch</h2><p>The CAM Patch is a long-term ambulatory ECG monitor that has been clinically proven to identify arrhythmias. It is engineered to optimize p-wave signal capture, which enables differentiation between different types of atrial, as well as ventricular, arrhythmias^{1, 2}. The CAM's simple design allows for ease of application and its clinical portal helps streamline clinician workflow.</p><p>Learn more about the CAM Patch solution.</p><p>Request More Information ></p></div> <div data-bbox="556 846 1881 915"><p>(https://www.hillrom.com/en/products/cam-patch/; <i>see also</i> https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf)</p></div> <div data-bbox="556 948 1881 1019"><p>The Bardy CAM Patch comprises long-term adhesion for the service life of the Patch “Up to 2, 7, or 14 days”</p></div>
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**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

Technical Specifications

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TECHNICAL SPECIFICATIONS

ITEM	SPECIFICATION
Performance Characteristics	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 days
Shelf life	24 months

<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

	<div data-bbox="577 235 1386 933"> <p>Carnation Ambulatory Monitor by Bardy Diagnostics</p> <p>Designed to be placed along the sternum — over the heart — to optimize P-wave signal capture, the CAM Patch results in improved ECG clarity, providing more information about heart rhythm that may lead to more clinically-actionable diagnoses compared to leading ECG monitors in the industry. Its unique form factor is designed with comfort and satisfaction in mind, with the aim of improving patient compliance.¹⁻⁴</p> <ul style="list-style-type: none"> Event button to mark the continuous recording of patient symptoms Proprietary circuit design enabling optimal signal-to-noise Lightweight and low-profile design Slim hourglass shape Durable long-term adhesive suitable for sensitive skin <p><small>Image represents actual size of Carnation Ambulatory Monitor</small></p> </div> <p>(https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf)</p>
<p>[1.a] a housing comprising a physiologic data collection circuit,</p>	<p>The Bardy CAM Patch product comprises a housing comprising a physiologic data collection circuit.</p> <p>For example, the Bardy CAM Patch product includes a physiological data collection circuit. A circuit in the Bardy CAM Patch collects physiological data, such as cardiac P-wave signals.</p>

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**



Carnation Ambulatory Monitor

by Bardy Diagnostics

Designed to be placed along the sternum — over the heart — to optimize P-wave signal capture, the **CAM Patch** results in improved ECG clarity, providing more information about heart rhythm that may lead to more clinically-actionable diagnoses compared to leading ECG monitors in the industry. Its unique form factor is designed with comfort and satisfaction in mind, with the aim of improving patient compliance.¹⁻⁴

Event button to mark the continuous recording of patient symptoms

Proprietary circuit design enabling optimal signal-to-noise

Lightweight and low-profile design

Slim hourglass shape

Durable long-term adhesive suitable for sensitive skin

Image represents actual size of Carnation Ambulatory Monitor

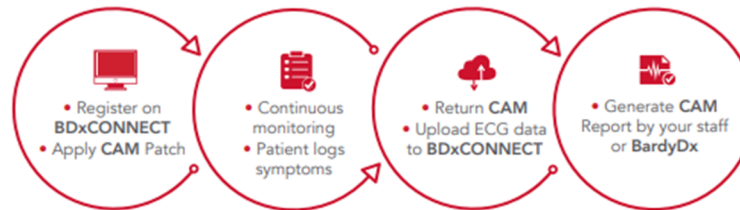


(<https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

Convenience for the Practice

Customizable Workflow to Fit the Needs of Your Practice¹

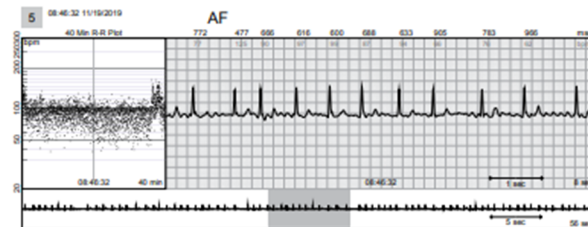


Increased Efficiency and Streamlined Clinical Workflows Using our Easy-to-Use Patient Management Portal⁴



Clarity for the Physician²

ECG Clarity That Improves Clinical Decision Making²⁻⁴



- High Diagnostic Yield for Informed Diagnoses¹⁻³
- 14 Days Extended Duration Monitoring
- Proprietary Report Format Delivers Clarity and Context¹

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

(<https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>)

Bardy CAM Patch product comprises a housing comprising a physiologic data collection circuit.



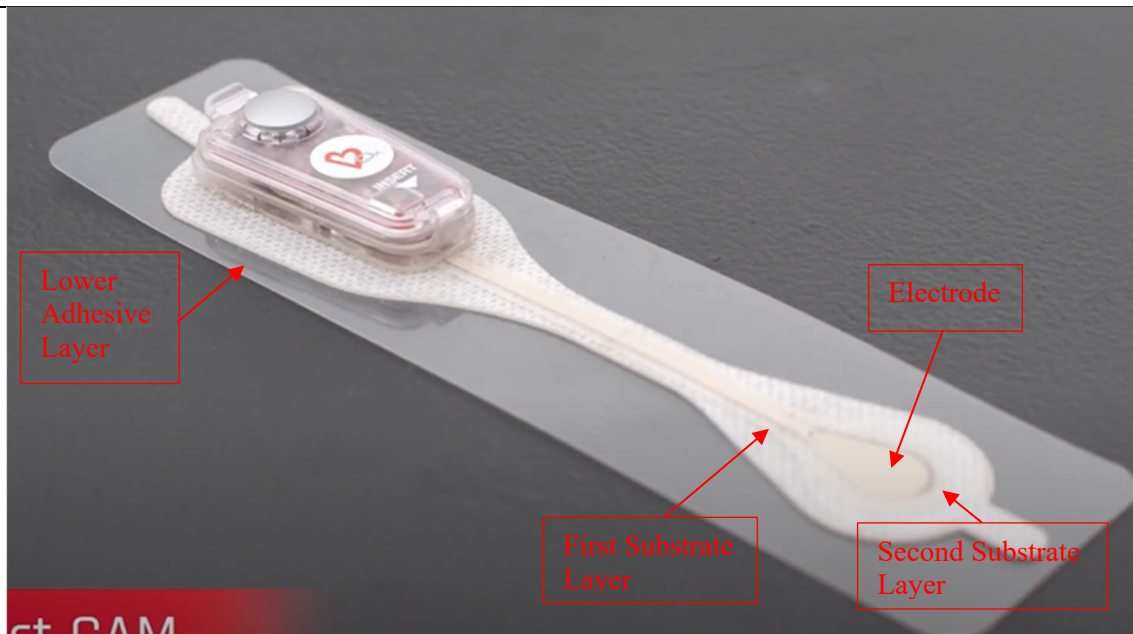
(<https://www.youtube.com/watch?v=RPcdb-volpc&t=123s>)

[1.b] an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface, the lower adhesive layer providing adhesion to the skin of the user;

The Bardy CAM Patch product comprises an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface, the lower adhesive layer providing adhesion to the skin of the user.

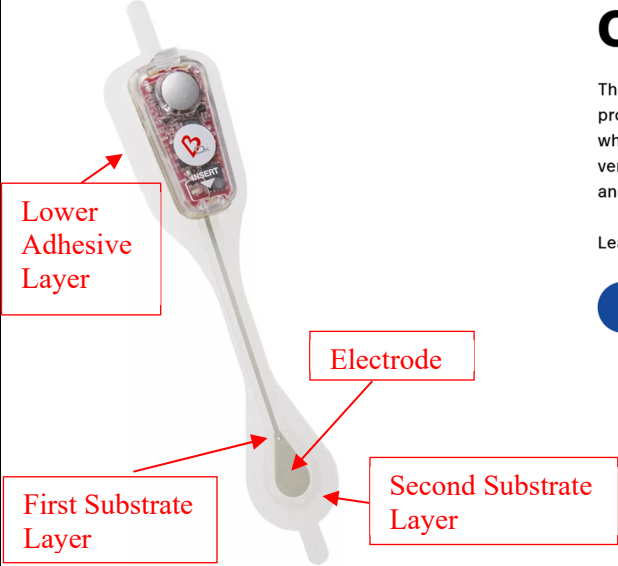
For example, the Bardy CAM Patch product comprises an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface.

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**



(<https://www.youtube.com/watch?v=RPcdb-volpc&t=123s>)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**



The diagram illustrates the Bardy CAM Patch, a long-term ambulatory ECG monitor. It features a central electrode connected to a lead wire. The patch is composed of several layers: a Lower Adhesive Layer at the top, followed by a First Substrate Layer, the Electrode in the center, and a Second Substrate Layer at the bottom. A small electronic device is attached to the top of the patch via the lead wire.

Baxter

CAM Patch

The CAM Patch is a long-term ambulatory ECG monitor that has been clinically proven to identify arrhythmias. It is engineered to optimize p-wave signal capture, which enables differentiation between different types of atrial, as well as ventricular, arrhythmias^{1, 2}. The CAM's simple design allows for ease of application and its clinical portal helps streamline clinician workflow.

Learn more about the [CAM Patch solution](#).

Request More Information >

[\(https://www.hillrom.com/en/products/cam-patch/\)](https://www.hillrom.com/en/products/cam-patch/)

Carnation Ambulatory Monitor (CAM®) Specifications

ELECTRODE CHARACTERISTICS	SPECIFICATION
ITEM	
Number of electrodes	2
Type	Electrode incorporating electrode gel and internal lead wire
Supplied as	Disposable, non-sterile
Lead wire length	11.6 cm (no patient contact)
Materials	Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive

[\(https://www.bardydx.com/wp-content/uploads/2025/01/DN000697B-BDx_CAM_SpecSheet.pdf\)](https://www.bardydx.com/wp-content/uploads/2025/01/DN000697B-BDx_CAM_SpecSheet.pdf)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

The lower adhesive layer of the Bardy CAM Patch product provides adhesion to the skin of the user.

Step 5

Gently peel the liner from the CAM by grasping the tab at the top of the device and peeling downward, carefully avoiding contact with the adhesive.



⚠ CAUTION: Touching the adhesive can reduce adhesive performance. Hold onto tabs at the end of the CAM.

(<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

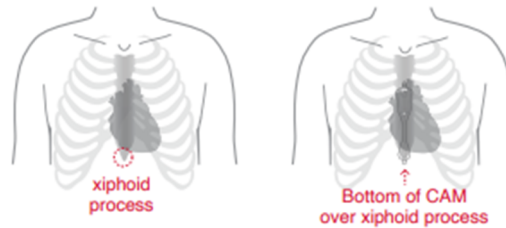
Instructions For Use

4

APPLY THE CAM

Step 6

Locate the bone at the bottom of the sternum. This is the xiphoid process.



Apply the CAM to the patient's sternum with the bottom electrode of the patch sitting over the xiphoid process. Press along the entire edge of the patch for 2 minutes and rub firmly around the edges of the patch for 1 minute to ensure adhesion. Place two fingers below the event button and press down firmly to adhere the top of the CAM to the patient's chest.

(<https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>)

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

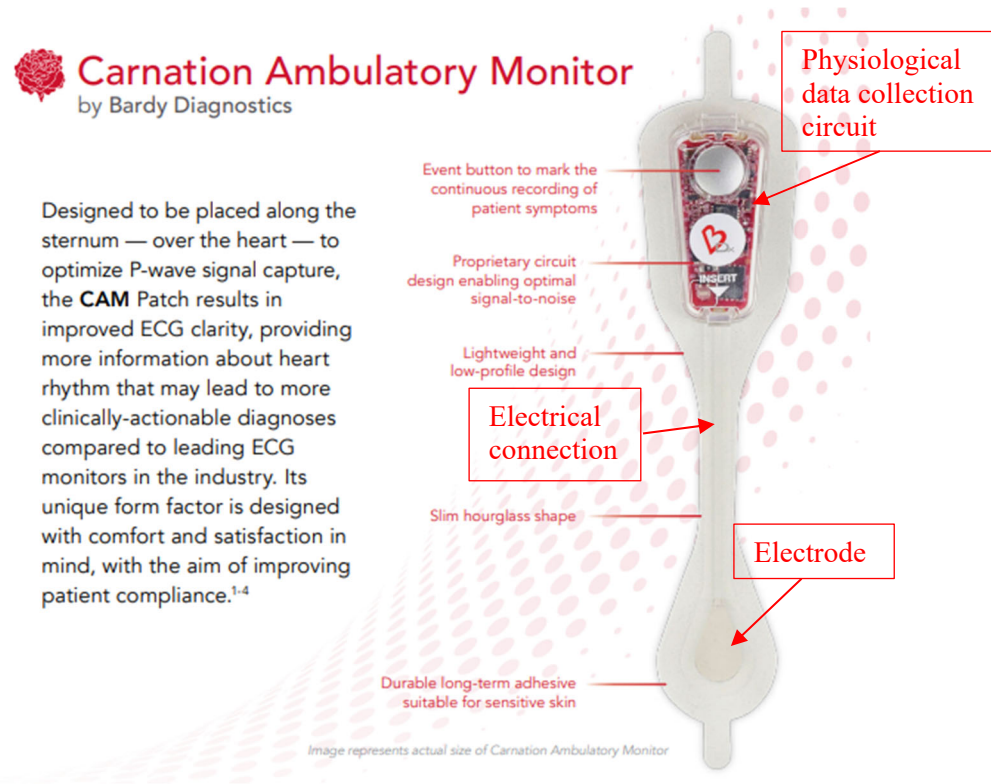
	<div data-bbox="569 240 730 516"> </div> <div data-bbox="709 233 1226 802"> </div> <div data-bbox="1287 233 1549 318"> <p>Baxter CAM Patch</p> </div> <div data-bbox="1287 339 1883 453"> <p>The CAM Patch is a long-term ambulatory ECG monitor that has been clinically proven to identify arrhythmias. It is engineered to optimize p-wave signal capture, which enables differentiation between different types of atrial, as well as ventricular, arrhythmias^{1, 2}. The CAM's simple design allows for ease of application and its clinical portal helps streamline clinician workflow.</p> </div> <div data-bbox="1287 475 1604 496"> <p>Learn more about the CAM Patch solution.</p> </div> <div data-bbox="1304 537 1572 581"> <p>Request More Information ></p> </div> <div data-bbox="548 842 1883 915"> <p>(https://www.hillrom.com/en/products/cam-patch/; see also https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf)</p> </div> <div data-bbox="554 943 1724 1292"> </div>
<p>[1.c] an electrode posi-</p>	<p>The Bardy CAM Patch product comprises an electrode positioned on the bottom surface of the electrode-</p>

**Infringement of U.S. Patent No. 12,303,277
By the Bardy CAM Patch Product**

tioned on the bottom surface of the electrode-supporting section, the electrode electrically connected to the physiologic data collection circuit; and

supporting section, the electrode electrically connected to the physiological data collection circuit.

For example, the Bardy CAM Patch comprises an electrode positioned on the bottom surface of the electrode-supporting section. The Bardy CAM Patch includes the electrode electrically connected to the physiological data collection circuit.



(<https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>)

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	<div data-bbox="598 235 1018 820"> <p>Physiologic data collection circuit</p> <p>Electrical connection</p> <p>Electrode</p> </div> <div data-bbox="1129 212 1795 581"> <p>Baxter</p> <p>CAM Patch</p> <p>The CAM Patch is a long-term ambulatory ECG monitor that has been clinically proven to identify arrhythmias. It is engineered to optimize p-wave signal capture, which enables differentiation between different types of atrial, as well as ventricular, arrhythmias^{1, 2}. The CAM's simple design allows for ease of application and its clinical portal helps streamline clinician workflow.</p> <p>Learn more about the CAM Patch solution.</p> <p>Request More Information ></p> </div> <div data-bbox="556 846 1207 885"> <p>(https://www.hillrom.com/en/products/cam-patch/)</p> </div> <div data-bbox="556 911 1726 1260"> <p>Electrode</p> <p>Electrical connection</p> <p>Physiologic data collection circuit</p> </div>
<p>[1.d] wherein the first substrate layer is positioned over the electrode</p>	<p>The Bardy CAM Patch product comprises wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode.</p>

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and extends horizontally away from the housing beyond a boundary of the electrode; and

For example, the Bardy CAM Patch includes a first substrate layer positioned over the electrode.



Carnation Ambulatory Monitor
by Bardy Diagnostics

Designed to be placed along the sternum — over the heart — to optimize P-wave signal capture, the **CAM** Patch results in improved ECG clarity, providing more information about heart rhythm that may lead to more clinically-actionable diagnoses compared to leading ECG monitors in the industry. Its unique form factor is designed with comfort and satisfaction in mind, with the aim of improving patient compliance.¹⁻⁴

Event button to mark the continuous recording of patient symptoms

Proprietary circuit design enabling optimal signal-to-noise

Lightweight and low-profile design

Slim hourglass shape

Electrode

Durable long-term adhesive suitable for sensitive skin

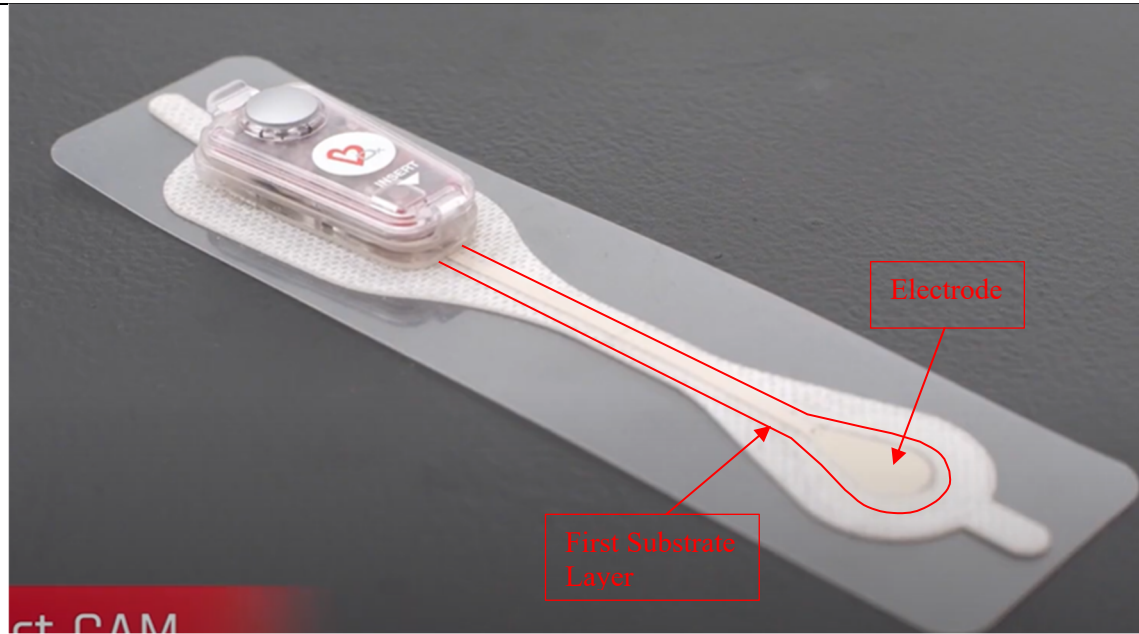
Image represents actual size of Carnation Ambulatory Monitor



First Substrate Layer

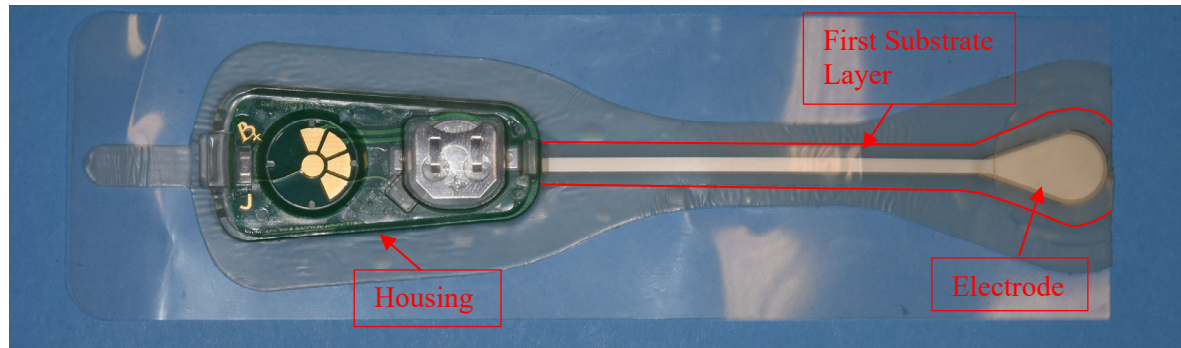
(<https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>)

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(<https://www.youtube.com/watch?v=RPcdb-volpc&t=123s>)

For example, the Bardy CAM Patch includes a first substrate layer that extends horizontally away from the housing beyond a boundary of the electrode.

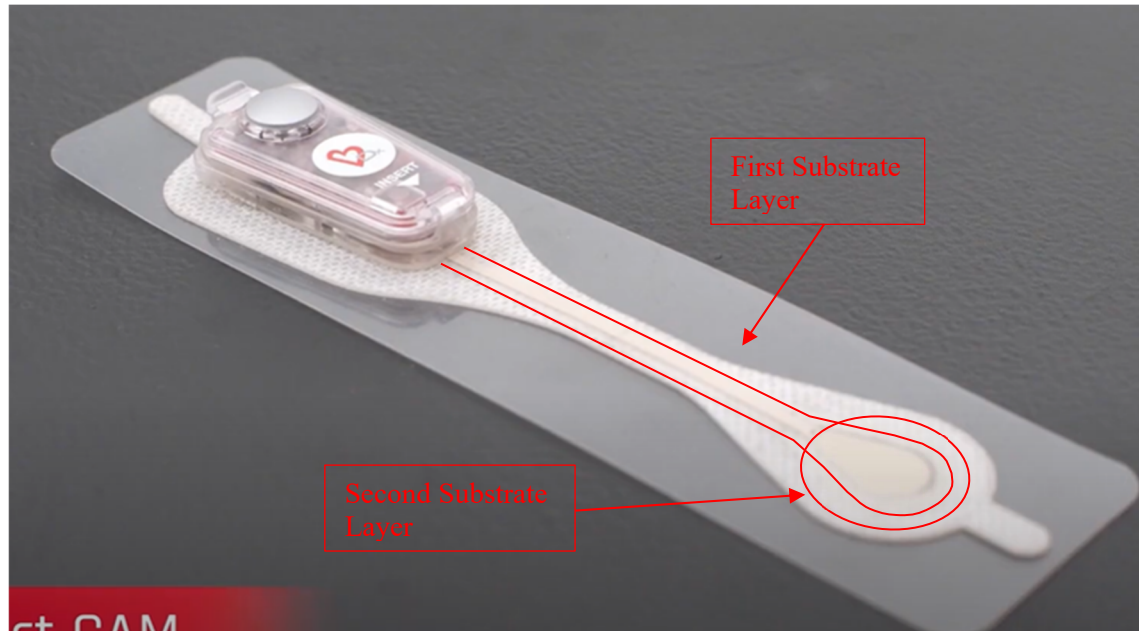


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[1.f] wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer.

The Bardy CAM product comprises wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer.

The Bardy CAM Patch product includes the second substrate layer is positioned over the first substrate layer as it extends horizontally beyond a boundary of the first substrate layer.



(<https://www.youtube.com/watch?v=RPcdb-volpc&t=123s>)

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